SEP 1 2 2008

K081569

Exhibit # 1

510(K) SUMMARY

THIS SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION IS BEING SUBMITTED IN ACCORDANCE WITH THE REQUIREMENTS OF THE SAFE MEDICAL DEVICES ACT OF 1990.

Submitter	Dynarex Corporation 10 Glenshaw Street Orangeburg, NY 10962 USA Phone: 845-365-8200 Fax: 845-365-8238
Contact Person	Vijay Sachdev
Date of Summary	05-12-2008
Trade Name	Non-sterile Dynarex / Tillotson Nitrile Powder Free Blue Patient Examination Glove, Tested for use with Chemotherapy Drugs.
Common Name	Dynarex / Tillotson Nitrile Powder Free Patient Examination Glove.
Classification Name	Dynarex / Tillotson Nitrile Powder Free Patient Examination Glove
Predicate Device	Shijiazhuang Tillotson Rubber Products Co., Ltd., China Non-Sterile Powder-Free Blue Nitrile Examination Glove, (K042378).
Device Description/ Comparison	Classified by FDA's General and Plastic Surgery Device panel as Class I, 21CFR 880.6250, Patient Examination Glove 80 LZA, and meets all requirements of ASTM Standard D6319-00a ε^3
Intended Use	**A patient examination glove is disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.** **In addition, these gloves are worn to protect the wearer against exposure to Chemotherapy Drugs.**

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Substantial Equivalence Discussion:
A powder free patient examination glove (Tested for Use with Chemotherapy Drugs) is substantially equivalent to the predicate devices.

Characteristic and parameters	Dynarex Corporationn (New Device)	Shijiazhuang Tillotson Rubber Products Co.,	MEDLINE
Product Code	LZA	LZA	LZA
Intended Use	A patient examination glove is disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves are worn to protect the wearer against exposure to Chemotherapy Drugs.	A patient examination glove is disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.	Medline Powder-Free Blue Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
Width (size medium)	96 mm	96 mm	92 mm
Overall length	230 mm	230 mm	240 mm
Palm thickness	0.08 mm	0.08 mm	0.17mm
Finger thickness	0.08 mm	0.08 mm	0.18rmm
Tensile strength pre aging min	14 Mpa	14 Mpa	21mpa
Tensile strength after aging min	14 Mpa	14 Mpa	16mpa
Ultimate elongation pre aging min	500 %	500 %	500 %
Ultimate elongation after aging min	450 %	450 %	500
Meets Biocompatibility standards	Yes	Yes	Yes
Duration of bio-compatibility	Limited	Limited	Limited
Skin irritation test	Passes	Passes	Passes
Dermal sensitization	Passes	Passes	Passes
Residual powder test	Passes	Passes	Passes

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Summary of Testing:

Test Results	
1. Dermal Sensitization Test	Passes
2. Primary Skin irritation	Passes
3. Permeation testing per ASTM D 6978-05	Passes
4. Water Leak Test	Passes
5. Dimensions (Length, Width, & Thickness) Test	Passes
6. Tensile strength (Before & after aging)	Gloves meets the requirements of ASTM D6319-00ae3.
7. Ultimate elongation (Before & after aging)	Gloves meets the requirements of ASTM D6319-00ae3

The standards used by Dynarex Corporation to determine substantial equivalence are based on ASTM D 6319-00ae3-2001. All testing meets requirements for physical specifications and dimensions conducted on gloves, Inspection level S-2, AQL 4.0 pinholes at AQL 2.5

There are special labeling claims "Tested for Chemotherapy". We do not claim our gloves to be hypoallergenic.

Conclusion:

Powder free Blue Nitrile Patient Examination Glove tested with chemotherapy drugs performance was equivalent to any other conventional method evaluated. Our evaluation concluded that our device raises no new issues of Safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2008

Mr. Vijay Sachdev
Quality Engineer
Dynarex Corporation
10 Glenshaw Street
Orangeburg, New York 10962

Re: K081569
Trade/Device Name: Non-Sterile Dynarex / Tillotson Nitrile Powder Free Blue Patient Examination Glove, Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: August 18, 2008
Received: August 21, 2008

Dear Mr. Sachdev:

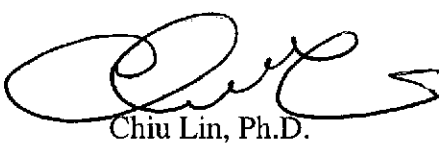
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 'A'

Indications for Use

510(k) Number (if known):

Device Name: Non-sterile Dynarex / Tillotson Nitrile Powder Free Blue Patient Examination Glove, Tested for use with Chemotherapy Drugs.

Indications For Use:

A patient examination glove is disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.
These gloves are tested for use with Chemotherapy Drugs.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila A. Murphy M.D.
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081569